

### **REMARKS**

Applicant notes with appreciation the withdrawal of the objection to the specification articulated in page 2, paragraph 2 of Paper No. 20050423, as well as the rejection of claims 9-14 under 35 U.S.C. §112, first paragraph, as articulated in pages 2-7 of Paper No. 20050423. Currently, claims 9-28 remain pending in the application. By way of this amendment claims 17 and 26-28 have been amended to identify the gram-positive bacterium being selected from the Markush group (claim 17) and to correct typographical and classification errors associated with the recitation of the target bacteria (claims 17 and 26-28). As such, it is submitted that no new matter has been added to the application by way of these amendments.

Currently, claims 9 and 10 stand rejected under 35 U.S.C. §102(b) over Loyola-Rodriguez et al. (of record). Claim 17 is objected to with respect to the informality of lack of capitalization and proper form of the bacterial genera; based on the amendments to claim 17 this objection is submitted to have been overcome. Claims 9-22 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Lastly, claims 17-28 stand rejected under 35 U.S.C. §112, second paragraph, for the recitation of pneumococci as an organism genus. In response to the rejection under 35 U.S.C. §112, second paragraph, claims 17 and 28 have been amended to recite the correct genus (and family) as *Streptococcus pneumoniae*. Upon entry of this amendment, the rejection as to claims 17-28 under 35 U.S.C. §112, second paragraph, is believed to have been overcome and as such, no rejections remain with respect to pending claims 23-28.

**Remarks Directed to Rejection of Claims 9 and 10 under  
35 U.S.C. §102(b) as Anticipated by Loyola-Rodriguez et al.**

The basis of this rejection was originally set forth in Paper No. 20050423 and reiterated in the outstanding Office Action at page 2 – page 4, section 4 (Paper No. 20051007).

The law as to inherent anticipation is well established in requiring that the missing element absolutely must be present in the thing described in the reference and not merely probable or possibly present. In *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1680, the court has stated:

Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element “is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). “Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

Applying the doctrine of inherency to pending claims 9 and 10 relative to Loyola-Rodriguez et al., Figure 1 of Loyola-Rodriguez et al. (right column, page 271) makes clear that the reference identifies a purified mutacin having a mass of greater than 6.2 kiloDaltons that is estimated to be 6.5 kiloDaltons (see abstract). Loyola-Rodriguez is silent as to a purified and isolated peptide having the sequence set forth in SEQ ID No: 2 of the pending claims or a pharmaceutically acceptable salt, amide, ester or prodrug thereof. Likewise, Loyola-Rodriguez is submitted to be silent as to administration of a SEQ ID No: 2 peptide to a subject for the purpose of treating or preventing a gram-positive infection.

Applicant agrees that Loyola-Rodriguez identifies mutacin MT6223 as a candidate for use in dental caries prevention and administration via drinking water per the abstract. However, this teaching is immaterial under the doctrine of inherency since for Loyola-Rodriguez et al. to anticipate pending claims 9 and 10 that reference would have to have the missing descriptive material as to SEQ ID No: 2 “necessarily present”, not merely probably or possibly present therein consistent with *Trintec Indus., Inc. v. Top-U.S.A. Corp.* as cited in *Rosco Inc. v. Mirror Lite Co.* above. As such, it is submitted that since the anticipatory rejection of claims 9 and 10 is devoid of an explanation how the SEQ ID No: 2 of the pending claims is necessarily present within mutacin MT6223, the outstanding anticipatory rejection is submitted to be improper and it is respectfully requested that it be withdrawn.

The fact that claim 9 is drafted with the transitory open-ended phrase “comprising” is immaterial and the novelty of that claim over Loyola-Rodriguez et al. absent an assertion how SEQ ID No: 2 of the pending claims is necessarily present within Loyola-Rodriguez et al. Therefore, Loyola-Rodriguez as a prior art reference does not anticipate since the peptide of SEQ ID NO. 2 is not necessarily present within Loyola-Rodriguez et al.

The Examiner’s basis for anticipation under inherency would be bolstered if mutacin MT6223 according to Loyola-Rodriguez et al. was a dimer, trimer or higher quaternary structure protein of which a subunit could be that of SEQ ID No: 2. However, neither the status of the field nor Loyola-Rodriguez et al. support the notion that mutacins are formed from peptide subunits.

In light of the above remarks, reconsideration and withdrawal of the rejection as to claims 9 and 10 under 35 U.S.C. §102(b) over Loyola-Rodriguez et al. is respectfully requested.

The attached declaration of Page Caufield submitted under 37 CFR 1.132 is submitted to support the supposition that the mutacin class of proteins are not formed of multiple peptide subunits.

**Remarks Directed to Rejection of  
Claims 9-22 under 35 U.S.C. §112, First Paragraph**

The basis of the rejection indicating failure to comply with the enablement requirement is that the claims are drawn to a method of treating or preventing all Gram-positive bacterial infections (citing O'Brien et al. as indicating Bacillus anthracis and Clostridium botulinum as microbes used in bioterrorism). (Paper No. 20051007, page 5). In support of enablement of pending claims 9-22, Applicants submit the declaration of coinventor Page Caufield inclusive of data indicating the effectiveness of that of SEQ ID No: 2 against a variety of Gram-positive bacteria including Staphylococcus pyogenes, Streptococcus pneumoniae, multiple drug resistant Staphylococcus aureus (MDRSA), vancomycin-resistant Enterococcus faecium, and Bacillus anthracis. Additionally, Applicant incorporates by reference the remarks made of record on July 28, 2005, pages 7-8.

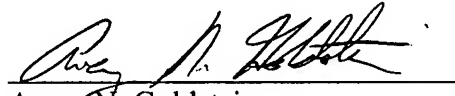
In light of the attached declaration indicating activity of the claimed invention against the broad spectrum of gram-positive bacteria including the most pathogenically aggressive forms, it is respectfully submitted that one of skill in the art would readily be able to test the efficacy and prepare an administrative composition for given gram-positive bacteria based on the teachings found within the specification as filed.

In light of the above remarks and the attached declaration of Page Caufield, reconsideration and withdrawal of the rejection as to pending claims 9-22 under 35 U.S.C. §112, first paragraph, for failure to comply with the enablement requirement is requested.

**Summary**

Entry of this amendment is respectfully requested in order to place the application in condition for allowance. By way of this amendment, claims 17 and 26-28 have been amended. Each claim is believed to be in allowable form and directed to patentable subject matter. Reconsideration and allowance of the pending claims is solicited. Should the Examiner have any suggestions as to how to improve the form of any of the pending claims, she is respectfully requested to contact the undersigned attorney responsible for this application to resolve any outstanding issues.

Respectfully submitted,

  
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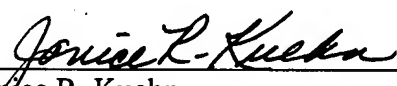
Reply to Office Action of October 19, 2005

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